

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-3, drawn to a method of treating a patient.

Group II, claim(s) 4 and 7-18, drawn to a pharmaceutical formulation.

Group III, claim(s) 19-23, drawn to an implant.

2. The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The special technical feature common to all of the groups cannot be considered a patentable advance over the art given that said feature, namely the formulation containing yttrium, neodymium, or zirconium, is old. For example, US Patent 4,610,241, cited in Applicant's International Search Report dated 8/3/04, discloses formulations containing yttrium useful in the treatment of atherosclerosis (see col. 1, lines 5-15 and col. 4, lines 17-34).

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

The pharmaceutical formulations according to claim 4 wherein the element(s) in the formulation is/are:

- A) yttrium,

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- B) neodymium,
- C) zirconium, or
- D) yttrium, neodymium, and zirconium;

and wherein the carrier is:

- E) an alloy, or
- F) a bioresorbable polymer.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable.

To clarify, Applicants must elect a single specie of element(s) chosen from choices A) – D), above, and must also elect a carrier chosen from choices E) and F), above.

The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The choices available for each of the elements and carriers for the formulations of claims 4 and 7-18 create combinations of formulations which vary significantly in structure and properties, so that the resulting formulations and/or methods of use would lack the same or corresponding special technical feature. For example, a formulation containing yttrium and an alloy would lack the same or corresponding technical feature as a formulation containing zirconium and a bioresorbable polymer.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara Frazier whose telephone number is (571)270-3496. The examiner can normally be reached on Monday-Thursday 8am-4pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718, or Cecilia Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BSF

/Ardin Marschel/  
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